[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket Nos. PRM-20-28, PRM-20-29, and PRM-20-30; NRC-2015-0057]

Linear No-Threshold Model and Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of docketing and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received three petitions for rulemaking (PRM) requesting that the NRC amend its "Standards for Protection Against Radiation" regulations and change the basis of those regulations from the Linear No-Threshold (LNT) model of radiation protection to the radiation hormesis model. The radiation hormesis model provides that exposure of the human body to low levels of ionizing radiation is beneficial and protects the human body against deleterious effects of high levels of radiation. Whereas, the LNT model provides that radiation is always considered harmful, there is no safety threshold, and biological damage caused by ionizing radiation (essentially the cancer risk) is directly proportional to the amount of radiation exposure to the human body (response linearity). The petitions were submitted by Carol S. Marcus, Mark L. Miller, and Mohan Doss (the petitioners), dated February 9, 2015, February 13, 2015, and February 24, 2015, respectively. These petitions were docketed by the NRC on February 20, 2015, February 27, 2015, and March 16, 2015, and have been assigned Docket Numbers. PRM-20-28, PRM-20-29, and PRM-20-30, respectively. The NRC is examining the issues raised in these petitions to determine whether they should be considered in rulemaking. The NRC is requesting public comments on these petitions for rulemaking.

DATES: Submit comments by **[INSERT DATE THAT IS 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2015-0057. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001;

telephone: 301-415-3781, e-mail: Solomon.Sahle@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments.

A. Obtaining Information.

Please refer to Docket ID NRC-2015-0057 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2015-0057.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments.

Please include Docket ID NRC-2015-0057 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. The Petitioners.

On February 9, 2015, Dr. Carol S. Marcus, a Professor of Radiation Oncology, of Molecular and Medical Pharmacology (Nuclear Medicine), and of Radiological Sciences at the David Geffen School of Medicine at the University of California-Los Angeles, filed a petition for rulemaking with the Commission, PRM-20-28 (ADAMS Accession No. ML15051A503). Dr. Marcus was a member of the NRC's Advisory Committee on the Medical Uses of Isotopes from 1990 to 1994. The petitioner indicated that "[t]here has never been scientifically valid support for this LNT hypothesis since its use was recommended by the U.S. National Academy of Sciences Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel in 1956" and that "[t]he costs of complying with these LNT based regulations are enormous."

On February 13, 2015, Mr. Mark L. Miller, a Certified Health Physicist, filed a petition for rulemaking with the Commission, PRM- 20-29 (ADAMS Accession No. ML15057A349). The petitioner indicated that "[t]here has never been scientifically valid support for this LNT hypothesis" and that "[t]he costs of complying with these LNT-based regulations are incalculable." In addition, the petitioner suggests that the use of the LNT hypothesis has "led to persistent radiophobia [radiation-phobia]."

On February 24, 2015, Dr. Mohan Doss, filed a petition for rulemaking with the Commission, PRM-20-30 (ADAMS Accession No. ML15075A200). Dr. Doss filed this petition on behalf of Scientist for Accurate Radiation Information, whose mission is to "help prevent unnecessary, radiation-phobia-related deaths, morbidity, and injuries associated with distrust of radio-medical diagnostics/therapies and from nuclear/radiological emergencies through countering phobia-promoting misinformation spread by alarmists via the news and other media including journal publications."

III. The Petition.

The petitioners request that the NRC amend part 20 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Standards for Protection Against Radiation," based on new science and evidence that contradicts the LNT hypothesis and request that the NRC greatly simplify and change 10 CFR part 20 to take into account the "vast literature demonstrating no effects or protective effects at relatively low doses of radiation." The NRC has determined that the petitions met the threshold sufficiency requirements for a petition for rulemaking under § 2.802, "Petition for rulemaking," and the petitions have been docketed as PRM-20-28, PRM-20-29, and PRM-20-30.

IV. Discussion of the Petitions.

A. PRM-20-28.

The petitioner, Dr. Carol S. Marcus, requests that the NRC amend its regulations in 10 CFR part 20 that are based on the LNT hypothesis. The petitioner states that "[t]his ultra-simplistic concept assumes that all radiation absorbed doses, no matter how small, have a finite probability of causing a fatal cancer." The petitioner further indicates that the "[u]se of the LNT assumption enables regulators to feel justified in ratcheting down permissible worker and public radiation levels, either through actual dose limits or use of the 'as low as reasonably achievable' (ALARA) principle, giving the illusion that they are making everyone safer (and creating ever increasing workload for themselves and their licensees)." However, the petitioner suggests that "there has never been scientifically valid support for this LNT hypothesis since its use was recommended by the U.S. National Academy of Sciences Committee on Biological Effects of Atomic Radiation (BEAR I)/Genetics Panel in 1956" and that the "costs of complying with these LNT based regulations are enormous."

The petitioner suggests that there is "vast literature" that demonstrates that low doses of radiation have no deleterious effect, and some studies even suggest that low doses of radiation may have protective effects. The petitioner writes, "[t]he literature showing protective effects supports the concept of hormesis, in which low levels of potentially stressful agents, such as toxins, other chemicals, ionizing radiation, etc., protect against the deleterious effects that high levels of these stressors produce and result in beneficial effects (e.g., lower cancer rates)." On May 16, 2015, the petitioner submitted an additional reference to the NRC providing technical information supporting her requests.[1]

The petitioner recommends the following changes to 10 CFR part 20:

[1] Siegel, Jeffry A., and Welsh, James S.: Does Imaging Technology Cause Cancer? Debunking the Linear No-Threshold Model of Radiation Carcinogenesis. *Technology in Cancer Research & Treatment* 1533034615578011, first published on March 30, 2015 doi:10.1177/1533034615578011.

1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.

2) ALARA should be removed entirely from the regulations. The petitioner argues that "it makes no sense to decrease radiation doses that are not only harmless but may be hormetic."

3) Public doses should be raised to worker doses. The petitioner notes that "these low doses may be hormetic. The petitioner goes on to ask, "why deprive the public of the benefits of low dose radiation?"

4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age.

B. PRM-20-29.

Similarly, the petitioner, Mr. Mark L. Miller, requests that the NRC amend its regulations in 10 CFR part 20 that are based on the LNT hypothesis. The petitioner used much of the same information used in Dr. Marcus' petition for rulemaking. However, Mr. Miller only requests that the following changes be made to 10 CFR part 20:

1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.

2) ALARA should be removed entirely from the regulations. The petitioner argues that "it makes no sense to decrease radiation doses that are not only harmless but may be hormetic."

3) Public doses should be raised to worker doses. The petitioner notes that "these low doses may be hormetic. The petitioner states, "[l]ow-dose limits for the public perpetuates radiophobia."

C. PRM-20-30.

The petition for rulemaking was submitted by Dr. Mohan Doss, on behalf of Scientist for Accurate Radiation Information, and "supports and supplements" petition PRM-20-28. This petitioner provides additional information suggesting that "low-dose radiation reduces cancer risk" (i.e., has a hormetic [beneficial] effect) and suggests that the "LNT model is no longer justifiable." The petitioner further states that the use of the LNT hypothesis in the NRC's regulations has "had a major detrimental effect on public health, since they have prevented the study of LDR [low-dose radiation] for controlling aging-related diseases such as cancer, Alzheimer's disease, Parkinson's disease, etc. in spite of studies showing the promise of LDR for the diseases." The petitioner suggests that "urgency of action on this petition" is necessary because "any potential future accident involving release of radioactive materials in the USA would likely result in panic evacuation because of the LNT - model-based cancer fears and concerns, resulting in considerable casualties and economic damage such as have occurred in Fukushima." The petitioner further suggests that the "recognition of a threshold dose by NRC would obviate the need for such panic evacuations, associated casualties, and economic harm" when radiation is released in the environment.

For additional information, see the filed petitions for rulemaking in ADAMS under Accession Nos. ML15051A503, ML15057A349, and ML15075A200.

V. Conclusion.

The NRC will examine the issues raised in PRM-20-28, PRM-20-29, and PRM-20-30 to determine whether they should be considered in rulemaking. The NRC is requesting public comments on these petitions for rulemaking.

Dated at Rockville, Maryland, this 16th day of June, 2015.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.